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SUMMARY OF SAFETY AND EFFECTIVENESS

The Irvine Biomedical, Inc. IBI-1100™ Steerable Electrophysiology Catheter System is a multiple-electrode electrophysiology recording catheter and its connecting cable. The diameter of the catheter is between 5 and 8 French. The diameter of the tip electrode is between 5 and 8 French.

The electrophysiology catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle. The IBI-1100™ Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies.

The components of the IBI-1100™ Steerable Electrophysiology Catheter System are all biocompatible and have all been tested for use in the body. Specifically, the patient contact materials are the same as the predicate devices and have been approved by the FDA. The sterilized, finished IBI-1100™ Steerable Electrophysiology Catheter has passed the biocompatibility and performance tests. Its manufacturing process will follow the Good Manufacturing Practice with quality assurance and validated sterilization process. Therefore, we believe the IBI-1100™ Steerable Electrophysiology Catheter on this submission to be safe and effective.

The accessory cables used to connect the IBI-1100™ Steerable Electrophysiology Catheters to a recorder are conventional and comply with Section 12A of the Underwriters Laboratories UL 544 Standard for Safety.